SUMMARY BASIS OF APPROVAL
ANDA 010228

Drug Product: Anticoagulant Citrate Dextrose Solution--Formula A, USP
Proprietary Name: None

Applicant: Gambro BCT, Inc.
10811 West Collins Avenue
Lakewood, CO 80215-4440

Dosage Form: Sterile Injection; Not for Direct Intravenous Infusion

Dispensed: Under prescription order (Rx); In 750 mL plastic containers.

Intended Use: Anticoagulant for blood collection.

Period of Marketing Exclusivity (re 21 CFR 314.94a(3)ii):

According to the information published in the list of Approved Drug Products with Therapeutic Equivalence Evaluations (*Orange Book*), Anticoagulant Citrate Dextrose Solution—Formula A, is not entitled to a period of marketing exclusivity under Section 505(j)4(D) of the Act.

Patent Certification and Exclusivity Statement (re 21 CFR 314.94(a)12(B)ii):

In the opinion and to the best knowledge of Gambro BCT, Inc., there are no patents that claim Anticoagulant Citrate Dextrose Solution—Formula A, or that claim a use for Anticoagulant Citrate Dextrose Solution—Formula A.

Potency: ---% to ---% of nominal (labeled)

Pharmacological Category:

USP, Anticoagulant

Regulatory Status:

The legally marketed drug product is listed as "Anticoagulant Citrate Dextrose Solution Formula -- A (ACDA)" on the list of Approved Drug Products with Therapeutic Equivalence Evaluations (*Orange Book*), under the section for Drug Products with Approval under Section 505 Administered by CBER.

The Reference Listed Drug authorization is held by Cutter Bio (N71497) and Travenol Labs (either N10855 or N16918, whichever is Solution A). The Reference Listed Drug is currently marketed by Baxter, Fenwal Division, under Code 4B7891, NDC 0942-0641-04.

Chemical Name and Structure:

($C_6H_8O_7$) ($C_6H_5Na_3O_7.-2H_2O$) ($NaH_2PO_4.-H_2O$) ($C_6H_{12}O_6.H_2O$)

Composition / Formula:

Ingredients	**Ref. Drug g / 100 mL**	**USP g / 100 mL**	**Gambro BCT g / 100 mL**
Citric Acid Anhydrous, USP	.073	0.73	0.73
Dextrose Monohydrate, USP	2.45	2.45	2.45
Sodium Citrate Dihydrate, USP	2.20	2.20	2.20
Water for Injection, in sufficient quantity to make:	100 mL	100 mL	100 mL

Bioavailability / Bioequivalence:

Evidence of bioavailability and bioequivalence is waived based on

- The product is a parenteral solution intended solely for administration by injection and;
- The product contains the same active and inactive ingredients in the same concentration as the approved NDA product.

Manufacturing Facilities:

Ivex Pharmaceuticals
Old Belfast Road
Millbrook, Larne
Co Antrim
BT40 2SH
Northern Ireland

Method of Sterilization: -------

Bags are filled with ACD-A in a Class ------- Clean Room under laminar air flow. After filling each bag is sealed with ----------. The filled bags are subsequently ---------- in ----------. These ---------- units are placed on sterilizer --------- following a specified loading pattern. A pre-sterilization bioburden sample is taken prior to the sterilization of each batch. The --------- sterilization process by ------- follows a predetermined, validated process. A number of parameters are monitored throughout the cycle.

Safety and Effectiveness:

The finding of safety and effectiveness is based on the equivalence of this product to the approved pioneer drug product and to the demonstration of compliance with Current Good Manufacturing Practices.